

CLAIM(S):

1. An intramedullary nail for treatment of a fracture of a bone having a medullary canal extending longitudinally, comprising:
 - a nail structure extending longitudinally and formed of metal with a first window defined in an exterior side of the nail structure, the first window having a first window longitudinal length and a first window width not equal to the first window longitudinal length; and
 - a first spacer formed of a non-metal material within the first window.
2. The intramedullary nail of claim 1, wherein the non-metal material of the first spacer is a bioresorbable material.
3. The intramedullary nail of claim 1, wherein the nail structure further comprises:
 - a second window defined in an exterior side of the nail structure opposing the first window permitting bicortical attachment with a bone fastener through the first and second windows, the second window having a second window longitudinal length and a second window width not equal to the second window longitudinal length.
4. The intramedullary nail of claim 3, wherein a second spacer formed of a non-metal material is within the second window.
5. The intramedullary nail of claim 4, wherein the nail structure further comprises a nail structure cannula defined longitudinally therein, wherein the first

PROVISIONAL

spacer and the second spacer are formed by a single insert with an insert cannula defined therethrough and aligned with the nail structure cannula.

6. The intramedullary nail of claim 3, wherein the nail structure includes a bend such that a longitudinal axis of the nail structure lies within a bisecting plane, and wherein the first window and the second window are symmetrically disposed on opposing sides of the bisecting plane.
 7. The intramedullary nail of claim 1, wherein the first window longitudinal length is greater than the first window width.
 8. The intramedullary nail of claim 1, wherein the nail structure further comprises a cannula defined longitudinally therein.
 9. The intramedullary nail of claim 1, wherein the first spacer fills the first window prior to anchoring of a bone fastener.
 10. The intramedullary nail of claim 1, wherein the first window is in a distal end of the nail structure, and wherein an additional bone attachment hole is defined in a proximal end of the nail structure.
 11. The intramedullary nail of claim 1, wherein the first window is in a distal end of the nail structure, and wherein the nail structure includes an opening longitudinally spaced from the first window and in the distal end of the nail structure.
 12. The intramedullary nail of claim 1, wherein the non-metal material of the first spacer is a bioresorbable material;

wherein the first window longitudinal length is greater than the first window width;

wherein the first window is in a distal end of the nail structure;
wherein the nail structure further comprises:

a second window defined in an exterior side of the nail structure opposing the first window permitting bicortical attachment with the bone fastener through the first and second windows, the second window having a second window longitudinal length and a second window width less than the second window longitudinal length;

a bend such that a longitudinal axis of the nail structure lies within a bisecting plane, wherein the first window and the second window are symmetrically disposed on opposing sides of the bisecting plane;

a nail structure cannula defined longitudinally in the nail structure;

a through-hole defined through the distal end of the nail structure and longitudinally spaced from the first and second windows; and

an additional bone attachment hole defined in a proximal end of the nail structure; and

wherein a bioresorbable insert provides the first spacer, the bioresorbable insert further providing a second spacer, the first spacer filling the first window and the second spacer filling the second window prior to anchoring a bone fastener through the first and second windows; and

wherein an insert cannula is defined through the bioresorbable insert and aligned with the nail structure cannula.

13. A method of forming an intramedullary nail, comprising the acts of:
forming a nail structure of metal with a first window defined in an
exterior side of the nail structure;
forming a first spacer of a non-metal material, with outer
dimensions which correspond to the first window; and
inserting the first spacer transversely into the first window to secure
the first spacer relative to the nail structure.
14. The method of claim 13, wherein the non-metal material of the first
spacer is a bioresorbable material.
15. The method of claim 13, wherein the first window is machined into
the nail structure with a first window longitudinal length and a first window width
not equal to the first window longitudinal length, and wherein the first spacer is
formed with a first spacer length corresponding to the first window longitudinal
length, and a first spacer width corresponding to the first window width and not
equal to the first spacer length.
16. The method of claim 15, wherein the first window longitudinal
length is greater than the first window width, and wherein the first spacer length is
greater than the first spacer width.
17. The method of claim 16, wherein the nail structure is formed with
a second window defined in an exterior side of the nail structure opposing the first
window, permitting bicortical attachment with a bone fastener through the first and
second windows, the second window having a second window longitudinal length
and a second window width which is less than the second window longitudinal
length.

P00042231P00060

18. The method of claim 17, further comprising:
forming a second spacer of a non-metal material; and
inserting the second spacer transversely into the second window.
19. The method of claim 18, wherein the first spacer and the second spacer are formed by a single insert placed into both the first and second windows from one side of the nail structure.
20. The method of claim 17, further comprising the act of forming a nail structure cannula in the nail structure, wherein the first spacer and the second spacer are formed by a single insert, and further comprising the act of forming an insert cannula through the single insert between the first spacer and the second spacer, and wherein the single insert is placed into both the first and second windows from one side of the nail structure such that the insert cannula aligns with the nail structure cannula.
21. A method of treating a fracture of a bone having a medullary canal extending longitudinally, comprising the acts of:
inserting an intramedullary nail longitudinally into the medullary canal, the intramedullary nail comprising:
a nail structure formed of metal with a first window defined in an exterior side of the nail structure, the first window having a first window longitudinal length and a first window width; and
a first spacer formed of a non-metal material within the first window; and
anchoring a bone fastener transversely through the bone and against the first spacer, the bone fastener having at least one of:

PCT/US2008/030001

- (a) a thickness which is less than the first window longitudinal length; and
 - (b) a width which is less than the first window width.
22. The method of claim 21, wherein the non-metal material of the first spacer is a bioresorbable material such that, upon increasing resorption of the first spacer, the bone fastener and intramedullary nail permit increasing dynamization of the fracture.
23. The method of claim 22, wherein the bone fastener has a thickness which is less than the first window longitudinal length and a width which generally corresponds to the first window width, such that, upon increasing resorption of the first spacer, the bone fastener permits increasing longitudinal dynamization of the nail structure with respect to the bone.
24. The method of claim 23, wherein the bone fastener is anchored at a distal end of the first window such that, upon increasing resorption of the first spacer, the bone screw permits increasing longitudinal dynamization of the nail structure with respect to the bone for compressive forces.
25. The method of claim 23, wherein the bone fastener is anchored through a middle of the first spacer such that, upon increasing resorption of the first spacer, the bone screw permits increasing longitudinal dynamization of the nail structure with respect to the bone for both compressive and tensile forces.
26. The method of claim 21, wherein the nail structure comprises:
a second window defined in an exterior side of the nail structure
opposing the first window, the second window having at least one of:

P A T E N T D E P A T E M E N T

- (a) a second window longitudinal length which is longer than the thickness of the bone fastener; and
- (b) a second window width which is wider than the width of the bone fastener;

and wherein the bone fastener is anchored through the first and second windows in bicortical attachment with the bone.

27. The method of claim 26, wherein a second spacer formed of a non-metal material is within the second window, and wherein the bone fastener is anchored against the second spacer.

28. The method of claim 21, wherein the first window longitudinal length is not equal to the first window width, wherein the bone fastener is a bone screw, and wherein the thickness and width of the bone fastener are equal diameters of the bone screw.

29. The method of claim 21, wherein the first window is in a distal end of the nail structure, and wherein the distal end of the nail structure includes an opening longitudinally spaced from the first window, and further comprising:
anchoring a second bone fastener transversely through the opening.

30. The method of claim 29, further comprising:
after an initial healing duration, removing the second bone fastener,
while leaving the bone fastener in place in the first window
for a complete healing duration.

31. A method of treating a fracture of a bone having a medullary canal extending longitudinally, comprising the acts of:

- DRAFTED BY GARDNER
- providing a nail structure formed of metal with a first window defined in an exterior side of the nail structure;
- providing an insert formed of a non-metal material separately from the nail structure, the insert being sized to fit within the first window;
- positioning the insert into the first window;
- inserting the nail structure together with the insert longitudinally into the medullary canal; and
- anchoring a bone fastener transversely through the bone and into the insert.
32. The method of claim 31, wherein the insert is provided as part of a kit having a plurality of inserts, each of the plurality of inserts having different mechanical or chemical treatment properties, and further comprising:
- selecting the insert to be used from among the plurality of inserts, the insert to be used having desired treatment properties for the fracture being treated.
33. The method of claim 32, wherein the different mechanical or chemical treatment properties are selected from the group consisting of: different hardnesses, different rates of absorption, different active agents and different amount of active agents.
34. The method of claim 31, further comprising:
- maintaining the insert in a controlled environment prior to the positioning of the insert into the first window.